NOV 0 7 2001

ALLIANCE
MEDICAL CORPORATION

K012611

510(k) Summary of Safety and Effectiveness

10232 South 51st Street
Phoenix, Arizona 85044

TEL 480.763.5300
FAX 480.763.5310
Toll Free 888.888.3433
www.alliance-medical.com

Submitter: Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact: Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation: 10 August 2001

Name of device: Reprocessed Arthroscopic Shavers

Common Name: Arthroscopic Shaver

Classification Name: Arthroscope

Reprocessed device(s):

Manufacturer	Description	Model
Dyonics®	Cutter	3439
Dyonics®	Cutter	3440
Dyonics®	Trimmer	3441
Dyonics®	Full Radius	3442
Dyonics®	Full Radius	3443
Dyonics®	Full Radius	3444
Dyonics®	Turbo Whisker	3446
Dyonics®	Turbo Trimmer	3529
Dyonics®	Incisor	3810
Dyonics®	Synovator	3826
Dyonics®	Synovator	4190
Dyonics®	Incisor	4191
Dyonics®	Razor Cut	4222
Dyonics®	Incisor	4223
Dyonics®	Razor Cut	4280
Dyonics®	Razor Cut	4284
Dyonics®	Full Radius	7205305
Dyonics®	Full Radius	7205306
Dyonics®	Full Radius	7205307
Dyonics®	Cutter	7205308
Dyonics®	Cutter	7205309
Dyonics®	Synovator	7205310
Dyonics®	Synovator	7205311
Dyonics®	Incisor	7205312
Dyonics®	Incisor	7205313
Dyonics®	Incisor	7205314

Dyonics®	Turbo Trimmer	7205315
Dyonics®	Turbo Whisker	7205316
Dyonics®	Razorcut	7205317
Dyonics®	Razorcut	7205318
Dyonics®	Razorcut	7205319
Dyonics®	Incisor	7205345
Dyonics®	Incisor	7205459

Predicate device(s):

K833587	Smith & Nephew Dyonics® Disposable Arthorscopy Blade
K904284	Smith & Nephew Dyonics® Arthroscopic Surgical Blade
K934229	Smith & Nephew Dyonics® Disposable Arthroscopic Surgery Blades
K953096	Smith & Nephew Dyonics® EP-1 Shaver
K953695	Smith & Nephew Dyonics® Disposable Arthroscopic Blades
K771218	Smith & Nephew Dyonics® Intra-Articular Shaver
K820367	Smith & Nephew Dyonics® Intra-Articular Surgical System
K971253	Smith & Nephew Dyonics® Endoscopic Surgery Blades
K900070	Smith & Nephew Dyonics® Modified Uses of the Arthroscopic Surgical System, Trimmer Blade and Full Radius Blade

Device description:

Arthroscopic shavers can be used to abrade, cut and excise tissue and bone; remove loose fragments; and shave away debris in arthroscopic surgeries, as well as surgeries of the jaw and sinuses.

The arthroscopic shaver components reprocessed by Alliance Medical Corporation include a bur or blade at the end of a long rod that rotates within a long hollow stainless steel housing. The housing has a window cut out on one side of the distal end, allowing the bur to cut one structure while the adjacent one is still protected by the housing on the opposite side of the bur or blade. This system attaches to a motorized handpiece that drives the internal bur or blade inside the outer housing and provides suction to pull the cut tissue away from the surgical site.

Intended use:

Reprocessed Arthroscopic Shavers are intended for resecting tissue and bone found in articular body cavities during orthopedic, maxillofacial, hand, foot and plastic surgery in patients requiring arthroscopic or orthopedic surgery.

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Indications statement:

Reprocessed arthroscopic shavers are indicated for use in orthopedic surgical procedures of the joints, jaw or sinuses where the cutting and removal of soft and hard tissue or bone is needed in patients requiring orthopedic surgery.

Technological characteristics:

The design, materials, and intended use of the Reprocessed Arthroscopic Shavers are identical to the predicate devices. The mechanism of action of the Reprocessed Arthroscopic Shaver is identical to the predicate devices in that the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Arthroscopic Shavers.

- Biocompatibility
- Validation of reprocessing
- Function test(s)

Performance testing demonstrates that Reprocessed Arthroscopic Shavers perform as originally intended.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (the Reprocessed Arthroscopic Shaver) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Mr. Don Selvey
Vice President, Regulatory Affairs
and Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K012611
Trade/Device Name: Alliance Medical Reprocessed Dyonics® Arthroscopic Shavers
Regulation Number: 888.1100
Regulation Name: Arthroscope and accessories
Regulatory Class: II
Product Code: HRX
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Welty for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 7 2001

INDICATIONS FOR USE

510(k) Number: K 012611

Device Name: Alliance Medical Corporation Reprocessed Arthroscopic Shavers

Indications for Use: The reprocessed arthroscopic shavers are indicated for use in orthopedic surgical procedures of the joints, jaw, or sinuses where the cutting and removal of soft and hard tissue or bone is needed in patients requiring orthopedic surgery.

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Dyonics	Synovator	3826
Dyonics	Synovator	4190
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Dyonics	Incisor	4223
Dyonics	Razor Cut	4280
Dyonics	Razor Cut	4284
Dyonics	Full Radius	7205305

Manufacturer	Description	Model
Dyonics	Full Radius	7205306
Dyonics	Full Radius	7205307
Dyonics	Cutter	7205308
Dyonics	Cutter	7205309
Dyonics	Synovator	7205310
Dyonics	Synovator	7205311
Dyonics	Incisor	7205312
Dyonics	Incisor	7205313
Dyonics	Incisor	7205314
Dyonics	Turbo Trimmer	7205315
Dyonics	Turbo Whisker	7205316
Dyonics	Razorcut	7205317
Dyonics	Razorcut	7205318
Dyonics	Razorcut	7205319
Dyonics	Orbit Synovator	7205321
Dyonics	Incisor	7205345
Dyonics	Incisor	7205459

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or **Over-the-Counter Use** ____
(Per 21 CFR 801.109)

Susan Walter

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012611